

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 3205
OFFERED BY MR. DEAL OF GEORGIA**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Patient Safety and Quality Improvement Act of 2005”.

4 (b) TABLE OF CONTENTS.—The table of contents for
5 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Amendments to Public Health Service Act.

“PART C—PATIENT SAFETY IMPROVEMENT

“Sec. 921. Definitions.

“Sec. 922. Privilege and Confidentiality Protections.

“Sec. 923. Network of Patient Safety Databases.

“Sec. 924. Patient Safety Organization Certification and Listing.

“Sec. 925. Technical Assistance.

“Sec. 926. Severability.”.

6 SEC. 2. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.

7 (a) IN GENERAL.—Title IX of the Public Health
8 Service Act (42 U.S.C. 299 et seq.) is amended—

9 (1) in section 912(c), by inserting “, in accord-
10 ance with part C,” after “The Director shall”;

11 (2) by redesignating part C as part D;

12 (3) by redesignating sections 921 through 928,
13 as sections 931 through 938, respectively;



1 (4) in section 938(1) (as so redesignated), by
2 striking “921” and inserting “931”; and

3 (5) by inserting after part B the following:

4 **“PART C—PATIENT SAFETY IMPROVEMENT**

5 **“SEC. 921. DEFINITIONS.**

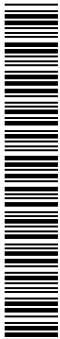
6 “In this part:

7 “(1) HIPAA CONFIDENTIALITY REGULA-
8 TIONS.—The term ‘HIPAA confidentiality regula-
9 tions’ means regulations promulgated under section
10 264(c) of the Health Insurance Portability and Ac-
11 countability Act of 1996 (Public Law 104–191; 110
12 Stat. 2033).

13 “(2) IDENTIFIABLE PATIENT SAFETY WORK
14 PRODUCT.—The term ‘identifiable patient safety
15 work product’ means patient safety work product
16 that—

17 “(A) is presented in a form and manner
18 that allows the identification of any provider
19 that is a subject of the work product, or any
20 providers that participate in activities that are
21 a subject of the work product;

22 “(B) constitutes individually identifiable
23 health information as that term is defined in
24 the HIPAA confidentiality regulations; or



1 “(C) is presented in a form and manner
2 that allows the identification of an individual
3 who reported information in the manner speci-
4 fied in section 922(e).

5 “(3) NONIDENTIFIABLE PATIENT SAFETY WORK
6 PRODUCT.—The term ‘nonidentifiable patient safety
7 work product’ means patient safety work product
8 that is not identifiable patient safety work product
9 (as defined in paragraph (2)).

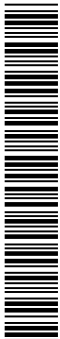
10 “(4) PATIENT SAFETY ORGANIZATION.—The
11 term ‘patient safety organization’ means a private or
12 public entity or component thereof that is listed by
13 the Secretary pursuant to section 924(d).

14 “(5) PATIENT SAFETY ACTIVITIES.—The term
15 ‘patient safety activities’ means the following activi-
16 ties:

17 “(A) Efforts to improve patient safety and
18 the quality of health care delivery.

19 “(B) The collection and analysis of patient
20 safety work product.

21 “(C) The development and dissemination
22 of information with respect to improving patient
23 safety, such as recommendations, protocols, or
24 information regarding best practices.



1 “(D) The utilization of patient safety work
2 product for the purposes of encouraging a cul-
3 ture of safety and of providing feedback and as-
4 sistance to effectively minimize patient risk.

5 “(E) The maintenance of procedures to
6 preserve confidentiality with respect to patient
7 safety work product.

8 “(F) The provision of appropriate security
9 measures with respect to patient safety work
10 product.

11 “(G) The utilization of qualified staff.

12 “(H) Activities related to the operation of
13 a patient safety evaluation system and to the
14 provision of feedback to participants in a pa-
15 tient safety evaluation system.

16 “(6) PATIENT SAFETY EVALUATION SYSTEM.—
17 The term ‘patient safety evaluation system’ means
18 the collection, management, or analysis of informa-
19 tion for reporting to or by a patient safety organiza-
20 tion.

21 “(7) PATIENT SAFETY WORK PRODUCT.—

22 “(A) IN GENERAL.—Except as provided in
23 subparagraph (B), the term ‘patient safety
24 work product’ means any data, reports, records,



1 memoranda, analyses (such as root cause anal-
2 yses), or written or oral statements—

3 “(i) which—

4 “(I) are assembled or developed
5 by a provider for reporting to a pa-
6 tient safety organization and are re-
7 ported to a patient safety organiza-
8 tion; or

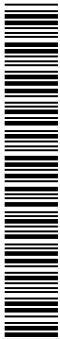
9 “(II) are developed by a patient
10 safety organization for the conduct of
11 patient safety activities;

12 and which could result in improved patient
13 safety, health care quality, or health care
14 outcomes; or

15 “(ii) which identify or constitute the
16 deliberations or analysis of, or identify the
17 fact of reporting pursuant to, a patient
18 safety evaluation system.

19 “(B) CLARIFICATION.—

20 “(i) Information described in subpara-
21 graph (A) does not include a patient’s
22 medical record, billing and discharge infor-
23 mation, or any other original patient or
24 provider record.



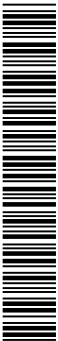
1 “(ii) Information described in sub-
2 paragraph (A) does not include informa-
3 tion that is collected, maintained, or devel-
4 oped separately, or exists separately, from
5 a patient safety evaluation system. Such
6 separate information or a copy thereof re-
7 ported to a patient safety organization
8 shall not by reason of its reporting be con-
9 sidered patient safety work product.

10 “(iii) Nothing in this part shall be
11 construed to limit—

12 “(I) the discovery of or admissi-
13 bility of information described in this
14 subparagraph in a criminal, civil, or
15 administrative proceeding;

16 “(II) the reporting of information
17 described in this subparagraph to a
18 Federal, State, or local governmental
19 agency for public health surveillance,
20 investigation, or other public health
21 purposes or health oversight purposes;
22 or

23 “(III) a provider’s recordkeeping
24 obligation with respect to information



1 described in this subparagraph under
2 Federal, State, or local law.

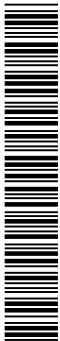
3 “(8) PROVIDER.—The term ‘provider’ means—

4 “(A) an individual or entity licensed or
5 otherwise authorized under State law to provide
6 health care services, including—

7 “(i) a hospital, nursing facility, com-
8 prehensive outpatient rehabilitation facil-
9 ity, home health agency, hospice program,
10 renal dialysis facility, ambulatory surgical
11 center, pharmacy, physician or health care
12 practitioner’s office, long term care facility,
13 behavior health residential treatment facil-
14 ity, clinical laboratory, or health center; or

15 “(ii) a physician, physician assistant,
16 nurse practitioner, clinical nurse specialist,
17 certified registered nurse anesthetist, cer-
18 tified nurse midwife, psychologist, certified
19 social worker, registered dietitian or nutri-
20 tion professional, physical or occupational
21 therapist, pharmacist, or other individual
22 health care practitioner; or

23 “(B) any other individual or entity speci-
24 fied in regulations promulgated by the Sec-
25 retary.



1 **“SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTEC-**
2 **TIONS.**

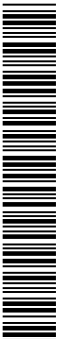
3 “(a) PRIVILEGE.—Notwithstanding any other provi-
4 sion of Federal, State, or local law, and subject to sub-
5 section (c), patient safety work product shall be privileged
6 and shall not be—

7 “(1) subject to a Federal, State, or local civil,
8 criminal, or administrative subpoena or order, in-
9 cluding in a Federal, State, or local civil or adminis-
10 trative disciplinary proceeding against a provider;

11 “(2) subject to discovery in connection with a
12 Federal, State, or local civil, criminal, or administra-
13 tive proceeding, including in a Federal, State, or
14 local civil or administrative disciplinary proceeding
15 against a provider;

16 “(3) subject to disclosure pursuant to section
17 552 of title 5, United States Code (commonly known
18 as the Freedom of Information Act) or any other
19 similar Federal, State, or local law;

20 “(4) admitted as evidence in any Federal,
21 State, or local governmental civil proceeding, crimi-
22 nal proceeding, administrative rulemaking pro-
23 ceeding, or administrative adjudicatory proceeding,
24 including any such proceeding against a provider; or



1 “(5) admitted in a professional disciplinary pro-
2 ceeding of a professional disciplinary body estab-
3 lished or specifically authorized under State law.

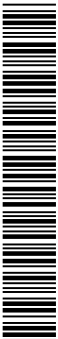
4 “(b) CONFIDENTIALITY OF PATIENT SAFETY WORK
5 PRODUCT.—Notwithstanding any other provision of Fed-
6 eral, State, or local law, and subject to subsection (c), pa-
7 tient safety work product shall be confidential and shall
8 not be disclosed.

9 “(c) EXCEPTIONS.—Except as provided in subsection
10 (g)(3)—

11 “(1) EXCEPTIONS FROM PRIVILEGE AND CON-
12 FIDENTIALITY.—Subsections (a) and (b) shall not
13 apply to (and shall not be construed to prohibit) one
14 or more of the following disclosures:

15 “(A) Disclosure of relevant patient safety
16 work product for use in a criminal proceeding,
17 but only after a court makes an in camera de-
18 termination that such patient safety work prod-
19 uct contains evidence of a criminal act and that
20 such patient safety work product is material to
21 the proceeding and not reasonably available
22 from any other source.

23 “(B) Disclosure of patient safety work
24 product to the extent required to carry out sub-
25 section (f)(4)(A).



1 “(C) Disclosure of identifiable patient safe-
2 ty work product if authorized by each provider
3 identified in such work product.

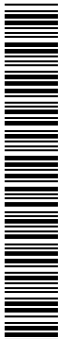
4 “(2) EXCEPTIONS FROM CONFIDENTIALITY.—
5 Subsection (b) shall not apply to (and shall not be
6 construed to prohibit) one or more of the following
7 disclosures:

8 “(A) Disclosure of patient safety work
9 product to carry out patient safety activities.

10 “(B) Disclosure of nonidentifiable patient
11 safety work product.

12 “(C) Disclosure of patient safety work
13 product to grantees, contractors, or other enti-
14 ties carrying out research, evaluation, or dem-
15 onstration projects authorized, funded, certified,
16 or otherwise sanctioned by rule or other means
17 by the Secretary, for the purpose of conducting
18 research to the extent that disclosure of pro-
19 tected health information would be allowed for
20 such purpose under the HIPAA confidentiality
21 regulations.

22 “(D) Disclosure by a provider to the Food
23 and Drug Administration with respect to a
24 product or activity regulated by the Food and
25 Drug Administration.



1 “(E) Voluntary disclosure of patient safety
2 work product by a provider to an accrediting
3 body that accredits that provider.

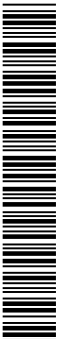
4 “(F) Disclosures that the Secretary may
5 determine, by rule or other means, are nec-
6 essary for business operations and are con-
7 sistent with the goals of this part.

8 “(G) Disclosure of patient safety work
9 product to law enforcement authorities relating
10 to the commission of a crime (or to an event
11 reasonably believed to be a crime) if the person
12 making the disclosure believes, reasonably
13 under the circumstances, that the patient safety
14 work product that is disclosed is necessary for
15 criminal law enforcement purposes.

16 “(H) With respect to a person other than
17 a patient safety organization, the disclosure of
18 patient safety work product that does not in-
19 clude materials that—

20 “(i) assess the quality of care of an
21 identifiable provider; or

22 “(ii) describe or pertain to one or
23 more actions or failures to act by an iden-
24 tifiable provider.



1 “(3) EXCEPTION FROM PRIVILEGE.—Subsection
2 (a) shall not apply to (and shall not be construed to
3 prohibit) voluntary disclosure of nonidentifiable pa-
4 tient safety work product.

5 “(d) CONTINUED PROTECTION OF INFORMATION
6 AFTER DISCLOSURE.—

7 “(1) IN GENERAL.—Patient safety work prod-
8 uct that is disclosed under subsection (c) shall con-
9 tinue to be privileged and confidential as provided
10 for in subsections (a) and (b), and such disclosure
11 shall not be treated as a waiver of privilege or con-
12 fidentiality, and the privileged and confidential na-
13 ture of such work product shall also apply to such
14 work product in the possession or control of a per-
15 son to whom such work product was disclosed.

16 “(2) EXCEPTION.—Notwithstanding paragraph
17 (1), and subject to paragraph (3)—

18 “(A) if patient safety work product is dis-
19 closed in a criminal proceeding, the confiden-
20 tiality protections provided for in subsection (b)
21 shall no longer apply to the work product so
22 disclosed; and

23 “(B) if patient safety work product is dis-
24 closed as provided for in subsection (c)(2)(B)
25 (relating to disclosure of nonidentifiable patient



1 safety work product), the privilege and con-
2 fidentiality protections provided for in sub-
3 sections (a) and (b) shall no longer apply to
4 such work product.

5 “(3) CONSTRUCTION.—Paragraph (2) shall not
6 be construed as terminating or limiting the privilege
7 or confidentiality protections provided for in sub-
8 section (a) or (b) with respect to patient safety work
9 product other than the specific patient safety work
10 product disclosed as provided for in subsection (c).

11 “(4) LIMITATIONS ON ACTIONS.—

12 “(A) PATIENT SAFETY ORGANIZATIONS.—

13 “(i) IN GENERAL.—A patient safety
14 organization shall not be compelled to dis-
15 close information collected or developed
16 under this part whether or not such infor-
17 mation is patient safety work product un-
18 less such information is identified, is not
19 patient safety work product, and is not
20 reasonably available from another source.

21 “(ii) NONAPPLICATION.—The limita-
22 tion contained in clause (i) shall not apply
23 in an action against a patient safety orga-
24 nization or with respect to disclosures pur-
25 suant to subsection (c)(1).



1 “(B) PROVIDERS.—An accrediting body shall
2 not take an accrediting action against a provider
3 based on the good faith participation of the provider
4 in the collection, development, reporting, or maintenance of patient safety work product in accordance
5 with this part. An accrediting body may not require
6 a provider to reveal its communications with any patient safety organization established in accordance
7 with this part.

10 “(e) REPORTER PROTECTION.—

11 “(1) IN GENERAL.—A provider may not take an
12 adverse employment action, as described in paragraph (2), against an individual based upon the fact
13 that the individual in good faith reported
14 information—

16 “(A) to the provider with the intention of
17 having the information reported to a patient
18 safety organization; or

19 “(B) directly to a patient safety organization.
20

21 “(2) ADVERSE EMPLOYMENT ACTION.—For
22 purposes of this subsection, an ‘adverse employment
23 action’ includes—

24 “(A) loss of employment, the failure to
25 promote an individual, or the failure to provide



1 any other employment-related benefit for which
2 the individual would otherwise be eligible; or

3 “(B) an adverse evaluation or decision
4 made in relation to accreditation, certification,
5 credentialing, or licensing of the individual.

6 “(f) ENFORCEMENT.—

7 “(1) CIVIL MONETARY PENALTY.—Subject to
8 paragraphs (2) and (3), a person who discloses iden-
9 tifiable patient safety work product in knowing or
10 reckless violation of subsection (b) shall be subject
11 to a civil monetary penalty of not more than
12 \$10,000 for each act constituting such violation.

13 “(2) PROCEDURE.—The provisions of section
14 1128A of the Social Security Act, other than sub-
15 sections (a) and (b) and the first sentence of sub-
16 section (c)(1), shall apply to civil money penalties
17 under this subsection in the same manner as such
18 provisions apply to a penalty or proceeding under
19 section 1128A of the Social Security Act.

20 “(3) RELATION TO HIPAA.—Penalties shall not
21 be imposed both under this subsection and under the
22 regulations issued pursuant to section 264(c)(1) of
23 the Health Insurance Portability and Accountability
24 Act of 1996 (42 U.S.C. 1320d-2 note) for a single
25 act or omission.



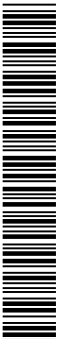
1 “(4) EQUITABLE RELIEF.—

2 “(A) IN GENERAL.—Without limiting rem-
3 edies available to other parties, a civil action
4 may be brought by any aggrieved individual to
5 enjoin any act or practice that violates sub-
6 section (e) and to obtain other appropriate eq-
7 uitable relief (including reinstatement, back
8 pay, and restoration of benefits) to redress such
9 violation.

10 “(B) AGAINST STATE EMPLOYEES.—An
11 entity that is a State or an agency of a State
12 government may not assert the privilege de-
13 scribed in subsection (a) unless before the time
14 of the assertion, the entity or, in the case of
15 and with respect to an agency, the State has
16 consented to be subject to an action described
17 in subparagraph (A), and that consent has re-
18 mained in effect.

19 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
20 tion shall be construed—

21 “(1) to limit the application of other Federal,
22 State, or local laws that provide greater privilege or
23 confidentiality protections than the privilege and
24 confidentiality protections provided for in this sec-
25 tion;



1 “(2) to limit, alter, or affect the requirements
2 of Federal, State, or local law pertaining to informa-
3 tion that is not privileged or confidential under this
4 section;

5 “(3) except as provided in subsection (i), to
6 alter or affect the implementation of any provision
7 of the HIPAA confidentiality regulations or section
8 1176 of the Social Security Act (or regulations pro-
9 mulgated under such section);

10 “(4) to limit the authority of any provider, pa-
11 tient safety organization, or other entity to enter
12 into a contract requiring greater confidentiality or
13 delegating authority to make a disclosure or use in
14 accordance with this section;

15 “(5) as preempting or otherwise affecting any
16 State law requiring a provider to report information
17 that is not patient safety work product; or

18 “(6) to limit, alter, or affect any requirement
19 for reporting to the Food and Drug Administration
20 information regarding the safety of a product or ac-
21 tivity regulated by the Food and Drug Administra-
22 tion.

23 “(h) CLARIFICATION.—Nothing in this part prohibits
24 any person from conducting additional analysis for any
25 purpose regardless of whether such additional analysis in-



1 involves issues identical to or similar to those for which in-
2 formation was reported to or assessed by a patient safety
3 organization or a patient safety evaluation system.

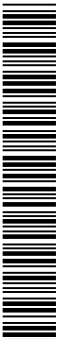
4 “(i) CLARIFICATION OF APPLICATION OF HIPAA CON-
5 FIDENTIALITY REGULATIONS TO PATIENT SAFETY ORGA-
6 NIZATIONS.—For purposes of applying the HIPAA con-
7 fidentiality regulations—

8 “(1) patient safety organizations shall be treat-
9 ed as business associates; and

10 “(2) patient safety activities of such organiza-
11 tions in relation to a provider are deemed to be
12 health care operations (as defined in such regula-
13 tions) of the provider.

14 “(j) REPORTS ON STRATEGIES TO IMPROVE PATIENT
15 SAFETY.—

16 “(1) DRAFT REPORT.—Not later than the date
17 that is 18 months after any network of patient safe-
18 ty databases is operational, the Secretary, in con-
19 sultation with the Director, shall prepare a draft re-
20 port on effective strategies for reducing medical er-
21 rors and increasing patient safety. The draft report
22 shall include any measure determined appropriate by
23 the Secretary to encourage the appropriate use of
24 such strategies, including use in any federally fund-
25 ed programs. The Secretary shall make the draft re-



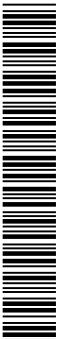
1 port available for public comment and submit the
2 draft report to the Institute of Medicine for review.

3 “(2) FINAL REPORT.—Not later than 1 year
4 after the date described in paragraph (1), the Sec-
5 retary shall submit a final report to the Congress.

6 **“SEC. 923. NETWORK OF PATIENT SAFETY DATABASES.**

7 “(a) IN GENERAL.—The Secretary shall facilitate the
8 creation of, and maintain, a network of patient safety
9 databases that provides an interactive evidence-based
10 management resource for providers, patient safety organi-
11 zations, and other entities. The network of databases shall
12 have the capacity to accept, aggregate across the network,
13 and analyze nonidentifiable patient safety work product
14 voluntarily reported by patient safety organizations, pro-
15 viders, or other entities. The Secretary shall assess the
16 feasibility of providing for a single point of access to the
17 network for qualified researchers for information aggre-
18 gated across the network and, if feasible, provide for im-
19 plementation.

20 “(b) DATA STANDARDS.—The Secretary may deter-
21 mine common formats for the reporting to and among the
22 network of patient safety databases maintained under sub-
23 section (a) of nonidentifiable patient safety work product,
24 including necessary work product elements, common and
25 consistent definitions, and a standardized computer inter-



1 face for the processing of such work product. To the ex-
2 tent practicable, such standards shall be consistent with
3 the administrative simplification provisions of part C of
4 title XI of the Social Security Act.

5 “(c) USE OF INFORMATION.—Information reported
6 to and among the network of patient safety databases
7 under subsection (a) shall be used to analyze national and
8 regional statistics, including trends and patterns of health
9 care errors. The information resulting from such analyses
10 shall be made available to the public and included in the
11 annual quality reports prepared under section 913(b)(2).

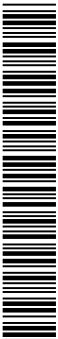
12 **“SEC. 924. PATIENT SAFETY ORGANIZATION CERTIFI-**
13 **CATION AND LISTING.**

14 “(a) CERTIFICATION.—

15 “(1) INITIAL CERTIFICATION.—An entity that
16 seeks to be a patient safety organization shall sub-
17 mit an initial certification to the Secretary that the
18 entity—

19 “(A) has policies and procedures in place
20 to perform each of the patient safety activities
21 described in section 921(5); and

22 “(B) upon being listed under subsection
23 (d), will comply with the criteria described in
24 subsection (b).



1 “(2) SUBSEQUENT CERTIFICATIONS.—An entity
2 that is a patient safety organization shall submit
3 every 3 years after the date of its initial listing
4 under subsection (d) a subsequent certification to
5 the Secretary that the entity—

6 “(A) is performing each of the patient
7 safety activities described in section 921(5); and

8 “(B) is complying with the criteria de-
9 scribed in subsection (b).

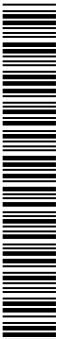
10 “(b) CRITERIA.—

11 “(1) IN GENERAL.—The following are criteria
12 for the initial and subsequent certification of an en-
13 tity as a patient safety organization:

14 “(A) The mission and primary activity of
15 the entity are to conduct activities that are to
16 improve patient safety and the quality of health
17 care delivery.

18 “(B) The entity has appropriately qualified
19 staff (whether directly or through contract), in-
20 cluding licensed or certified medical profes-
21 sionals.

22 “(C) The entity, within each 24-month pe-
23 riod that begins after the date of the initial list-
24 ing under subsection (d), has bona fide con-
25 tracts, each of a reasonable period of time, with



1 more than 1 provider for the purpose of receiv-
2 ing and reviewing patient safety work product.

3 “(D) The entity is not, and is not a com-
4 ponent of, a health insurance issuer (as defined
5 in section 2791(b)(2)).

6 “(E) The entity shall fully disclose—

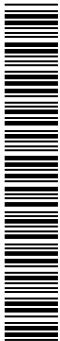
7 “(i) any financial, reporting, or con-
8 tractual relationship between the entity
9 and any provider that contracts with the
10 entity; and

11 “(ii) if applicable, the fact that the
12 entity is not managed, controlled, and op-
13 erated independently from any provider
14 that contracts with the entity.

15 “(F) To the extent practical and appro-
16 priate, the entity collects patient safety work
17 product from providers in a standardized man-
18 ner that permits valid comparisons of similar
19 cases among similar providers.

20 “(G) The utilization of patient safety work
21 product for the purpose of providing direct
22 feedback and assistance to providers to effec-
23 tively minimize patient risk.

24 “(2) ADDITIONAL CRITERIA FOR COMPONENT
25 ORGANIZATIONS.—If an entity that seeks to be a pa-



1 tient safety organization is a component of another
2 organization, the following are additional criteria for
3 the initial and subsequent certification of the entity
4 as a patient safety organization:

5 “(A) The entity maintains patient safety
6 work product separately from the rest of the or-
7 ganization, and establishes appropriate security
8 measures to maintain the confidentiality of the
9 patient safety work product.

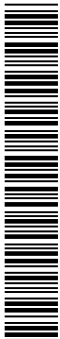
10 “(B) The entity does not make an unau-
11 thorized disclosure under this part of patient
12 safety work product to the rest of the organiza-
13 tion in breach of confidentiality.

14 “(C) The mission of the entity does not
15 create a conflict of interest with the rest of the
16 organization.

17 “(c) REVIEW OF CERTIFICATION.—

18 “(1) IN GENERAL.—

19 “(A) INITIAL CERTIFICATION.—Upon the
20 submission by an entity of an initial certifi-
21 cation under subsection (a)(1), the Secretary
22 shall determine if the certification meets the re-
23 quirements of subparagraphs (A) and (B) of
24 such subsection.



1 “(B) SUBSEQUENT CERTIFICATION.—

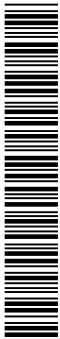
2 Upon the submission by an entity of a subse-
3 quent certification under subsection (a)(2), the
4 Secretary shall review the certification with re-
5 spect to requirements of subparagraphs (A) and
6 (B) of such subsection.

7 “(2) NOTICE OF ACCEPTANCE OR NON-ACCEPT-
8 ANCE.—If the Secretary determines that—

9 “(A) an entity’s initial certification meets
10 requirements referred to in paragraph (1)(A),
11 the Secretary shall notify the entity of the ac-
12 ceptance of such certification; or

13 “(B) an entity’s initial certification does
14 not meet such requirements, the Secretary shall
15 notify the entity that such certification is not
16 accepted and the reasons therefor.

17 “(3) DISCLOSURES REGARDING RELATIONSHIP
18 TO PROVIDERS.—The Secretary shall consider any
19 disclosures under subsection (b)(1)(E) by an entity
20 and shall make public findings on whether the entity
21 can fairly and accurately perform the patient safety
22 activities of a patient safety organization. The Sec-
23 retary shall take those findings into consideration in
24 determining whether to accept the entity’s initial
25 certification and any subsequent certification sub-



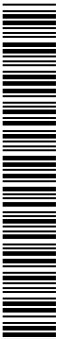
1 mitted under subsection (a) and, based on those
2 findings, may deny, condition, or revoke acceptance
3 of the entity's certification.

4 “(d) LISTING.—The Secretary shall compile and
5 maintain a listing of entities with respect to which there
6 is an acceptance of a certification pursuant to subsection
7 (c)(2)(A) that has not been revoked under subsection (e)
8 or voluntarily relinquished.

9 “(e) REVOCATION OF ACCEPTANCE OF CERTIFI-
10 CATION.—

11 “(1) IN GENERAL.—If, after notice of defi-
12 ciency, an opportunity for a hearing, and a reason-
13 able opportunity for correction, the Secretary deter-
14 mines that a patient safety organization does not
15 meet the certification requirements under subsection
16 (a)(2), including subparagraphs (A) and (B) of such
17 subsection, the Secretary shall revoke the Sec-
18 retary's acceptance of the certification of such orga-
19 nization.

20 “(2) SUPPLYING CONFIRMATION OF NOTIFICA-
21 TION TO PROVIDERS.—Within 15 days of a revoca-
22 tion under paragraph (1), a patient safety organiza-
23 tion shall submit to the Secretary a confirmation
24 that the organization has taken all reasonable ac-
25 tions to notify each provider whose patient safety



1 work product is collected or analyzed by the organi-
2 zation of such revocation.

3 “(3) PUBLICATION OF DECISION.—If the Sec-
4 retary revokes the certification of an organization
5 under paragraph (1), the Secretary shall—

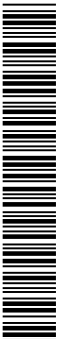
6 “(A) remove the organization from the list-
7 ing maintained under subsection (d); and

8 “(B) publish notice of the revocation in the
9 Federal Register.

10 “(f) STATUS OF DATA AFTER REMOVAL FROM LIST-
11 ING.—

12 “(1) NEW DATA.—With respect to the privilege
13 and confidentiality protections described in section
14 922, data submitted to an entity within 30 days
15 after the entity is removed from the listing under
16 subsection (e)(3)(A) shall have the same status as
17 data submitted while the entity was still listed.

18 “(2) PROTECTION TO CONTINUE TO APPLY.—If
19 the privilege and confidentiality protections de-
20 scribed in section 922 applied to patient safety work
21 product while an entity was listed, or to data de-
22 scribed in paragraph (1), such protections shall con-
23 tinue to apply to such work product or data after
24 the entity is removed from the listing under sub-
25 section (e)(3)(A).



1 “(g) DISPOSITION OF WORK PRODUCT AND DATA.—
2 If the Secretary removes a patient safety organization
3 from the listing as provided for in subsection (e)(3)(A),
4 with respect to the patient safety work product or data
5 described in subsection (f)(1) that the patient safety orga-
6 nization received from another entity, such former patient
7 safety organization shall—

8 “(1) with the approval of the other entity and
9 a patient safety organization, transfer such work
10 product or data to such patient safety organization;

11 “(2) return such work product or data to the
12 entity that submitted the work product or data; or

13 “(3) if returning such work product or data to
14 such entity is not practicable, destroy such work
15 product or data.

16 **“SEC. 925. TECHNICAL ASSISTANCE.**

17 “The Secretary, acting through the Director, may
18 provide technical assistance to patient safety organiza-
19 tions, including convening annual meetings for patient
20 safety organizations to discuss methodology, communica-
21 tion, data collection, or privacy concerns.

22 **“SEC. 926. SEVERABILITY.**

23 “If any provision of this part is held to be unconstitu-
24 tional, the remainder of this part shall not be affected.”.



1 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
2 937 of the Public Health Service Act (as redesignated by
3 subsection (a)) is amended by adding at the end the fol-
4 lowing:

5 “(e) PATIENT SAFETY AND QUALITY IMPROVE-
6 MENT.—For the purpose of carrying out part C, there are
7 authorized to be appropriated such sums as may be nec-
8 essary for each of the fiscal years 2006 through 2010.”.

9 (c) GAO STUDY ON IMPLEMENTATION.—

10 (1) STUDY.—The Comptroller General of the
11 United States shall conduct a study on the effective-
12 ness of part C of title IX of the Public Health Serv-
13 ice Act (as added by subsection (a)) in accom-
14 plishing the purposes of such part.

15 (2) REPORT.—Not later than February 1,
16 2010, the Comptroller General shall submit a report
17 on the study conducted under paragraph (1). Such
18 report shall include such recommendations for
19 changes in such part as the Comptroller General
20 deems appropriate.

